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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,615	EGGERMONT ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/05, 8/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on December 23, 2003. It is noted, however, that applicant has not filed a certified copy of the 2,451,929 application as required by 35 U.S.C. 119(b).

Claim Objections

2. Claims 1-15 are objected to because of the following informalities:

In regards to claim 1, at line 8, the limitations "the acoustic response" lack antecedent basis and apparently should read --the response-- as per line 3. See repeated occurrences in claim 5, at lines 1 and 3, claim 9, at lines 2 & 4.

Further in regard to claim 1, the method appears to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. The omitted step includes a step disclosing how to detect an abnormal response.

In regards to claim 5, at line 2, the limitations "the auditory brainstem response" lack antecedent basis and apparently should read --an auditory brainstem response--.

In regards to claim 7, at line 8, the limitations "the next highest" renders the claim indefinite; it is unclear whether or not the response in the highest frequency range, as per line 6, is lower or higher; moreover, it is unclear whether or not the response strength directly correlates with the frequency range.

In regards to claims 8 and 13, the method essentially is a "used" claim that includes an intended use statement without explicitly disclosing how the step should be

carried out, which essentially amounts to a missing step wherein the step comprises how to predict the existence of tumor.

In regards to claim 9, at line 5, "the ratio" should apparently read --a ratio--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 9, 11-12, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by John et al. (US Patent No. 6,385,486).

In regards to claim 1, John et al. disclose(s) a method of detecting an abnormal response, the method comprising the steps of:

A) receiving a response generated by applying a stimulus to a body, the response comprising a complete set of frequencies;

B) combining transforms of each of plural subsets of the complete set of frequencies; and

C) comparing the combined transforms found in step B with a transform of the complete set of frequencies in the acoustic response (see fig. 1; column 3/lines 55-60; column 4/lines 35-42, 53-55 & 60-62; column 6/lines 50-62; column 8/lines 27-44 & 55-63; column 9/lines 16-28 & 30-47; column 12/lines 28-42 & 45-51; column 13/lines 2-5).

In regards to claim 2, John et al. disclose(s) a method in which the transform is a transform that results in a power spectrum of the frequencies contained in the response (see fig. 1; column 3/lines 55-60; column 4/lines 35-42, 53-55 & 60-62; column 6/lines 50-62; column 8/lines 27-44 & 55-63; column 9/lines 16-28 & 30-47; column 12/lines 28-42 & 45-51; column 13/lines 2-5).

In regards to claim 3, John et al. disclose(s) a method in which the response is an acoustic brainstem response generated by applying a stimulus to an ear (column 4/lines 2-9; column 8/lines 33-36; column 13/lines 19-22; column 14/lines 41-47).

In regards to claim 4, John et al. disclose(s) a method in which combining transforms comprises the steps of:

B1) finding a transform of each of plural subsets of the set of frequencies; and

B2) summing the transforms found in step B1 (see fig. 1; column 3/lines 55-60; column 4/lines 35-42, 53-55 & 60-62; column 6/lines 50-62; column 8/lines 55-63; column 9/lines 16-28 & 30-47; column 12/lines 28-42 & 45-51; column 13/lines 2-5).

In regards to claim 5, John et al. disclose(s) a method in which the transform is a transform that results in a power spectrum of the frequencies contained in the response (see fig. 1; column 3/lines 55-60; column 4/lines 35-42, 53-55 & 60-62; column 6/lines 50-62; column 8/lines 55-63; column 9/lines 16-28 & 30-47; column 12/lines 28-42 & 45-51; column 13/lines 2-5).

In regards to claim 9, John et al. disclose(s) a method in which comparing the sum of power spectra with the power spectrum of the set of frequencies in the acoustic response comprises normalizing the sum of power spectra to obtain a normalized sum

and normalizing the power spectrum of the set of frequencies in the acoustic response to obtain a normalized reference and taking the ratio of the normalized sum and the normalized reference (see column 4/lines 35-42; column 10/lines 61-65; column 12/lines 28-42; column 13/line 36-42).

In regards to claim 11, John et al. disclose(s) a method further comprising the step of comparing the ratio of the normalized sum and the normalized reference to a ratio obtained from a group of people without abnormal auditory brainstem response (see column 4/lines 35-42; column 10/lines 61-65; column 12/lines 28-42; column 13/line 36-42).

In regards to claim 12, John et al. disclose(s) a method further comprising the step of comparing the ratio of the normalized sum and the normalized reference to a ratio obtained from the opposite ear of an individual (see column 4/lines 35-42; column 10/lines 61-65; column 12/lines 28-42; column 13/line 36-42).

In regards to claim 15, John et al. disclose(s) a method in which a combination of the plural subsets of the complete set of frequencies comprises a wide band response (see fig. 1; column 3/lines 31-47 & 55-60; column 4/lines 35-42, 53-55 & 60-62; column 6/lines 50-62; column 8/lines 27-44 & 55-63; column 9/lines 16-28 & 30-47; column 12/lines 28-42 & 45-51; column 13/lines 2-5).

In regards to claim 16 and 20, John et al. disclose(s) an apparatus for detecting abnormal auditory brainstem response, the apparatus comprising:

means for producing a broadband stimulus;

electrodes for sensing an auditory brainstem response; and

a processor connected to receive the auditory brainstem response, the processor being programmed to:

A) receive an acoustic response generated by applying a stimulus to an ear, the acoustic response comprising a set of frequencies;

B) find a power spectrum for each of plural subsets of the set of frequencies;

C) sum the power spectra found in step B; and

D) compare the sum of the power spectra found in step C with the power spectrum of the set of frequencies in the acoustic response (see fig. 1; column 3/lines 55-60; column 4/lines 2-9 & 35-42, 53-55 & 60-62; column 6/lines 50-62; column 8/lines 27-44, 33-36 & 55-63; column 9/lines 16-28 & 30-47; column 12/lines 28-42 & 45-51; column 13/lines 2-5 & 19-22; column 14/lines 41-47).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Don (US Patent No. 6,264,616) in view of Devito (US Patent No. 6,001,065).

In regards to claim 1, Don disclose(s) a method of detecting an abnormal response, the method comprising the steps of:

A) receiving a response generated by applying a stimulus to a body, the response comprising a complete set of frequencies (see column 5/lines 45-52).

In regards to claim 3, Don disclose(s) a method in which the response is an acoustic brainstem response generated by applying a stimulus to an ear (see column 5/lines 45-52).

In regards to claim 6, Don discloses a method in which the subset of frequencies of the acoustic response comprises the auditory brainstem response in a set of limited frequency ranges found by masking the acoustic response with white noise (see fig. 2; abstract; column 5/lines 63-64; column 7/lines 6-11 & 14-23).

In regards to claim 7, Don discloses a method in which the subsets of the complete set of frequencies are found by the steps of:

obtaining an unmasked acoustic response;

obtaining masked acoustic responses by masking the stimulus with white noise in a frequency range;

subtracting the masked acoustic response of the highest frequency range from the unmasked frequency response to obtain a subset of the set of frequencies; and

subtracting the masked acoustic response from the next highest masked acoustic response for the remaining frequency ranges (see fig. 2; abstract; column 5/lines 63-64; column 7/lines 6-11 & 14-23).

In regards to claim 8, Don disclose(s) a method in which the method is used to predict the existence of a tumor (see figs. 1 & 15; abstract).

In regards to claim 13, Don disclose(s) a method in which a peak in the range between 500 to 700 Hz is used as a predictor of the presence of a tumor (see fig. 2).

In regards to claim 14, Don disclose(s) a method in which the acoustic response is received differentially between a first electrode on the mastoid corresponding to the stimulated ear and a second electrode (see column 5/lines 45-52).

In regards to claim 16, Don disclose(s) an apparatus for detecting abnormal auditory brainstem response, the apparatus comprising:

means for producing a broadband stimulus;

electrodes for sensing an auditory brainstem response; and

a processor connected to receive the auditory brainstem response, the processor being programmed to:

A) receive an acoustic response generated by applying a stimulus to an ear, the acoustic response comprising a set of frequencies (see column 5/lines 45-56; column 6/lines 11-14).

In regards to claim 17, Don disclose(s) an apparatus in which the subset of frequencies of the acoustic response comprises the auditory brainstem response in a set of limited frequency ranges found by masking the acoustic response (see fig. 2; abstract; column 5/lines 63-64; column 7/lines 6-11 & 14-23).

In regards to claim 18, Don disclose(s) an apparatus in which the processor is further programmed to find the plural subsets of the set of frequencies by the steps of:

a) obtaining an unmasked acoustic response;

b) obtaining masked acoustic responses by masking the stimulus with white noise in a frequency range;

c) subtracting the masked acoustic response of the highest frequency range from the unmasked frequency response to obtain a subset of the set of frequencies; and

d) subtracting the masked acoustic response from the next highest masked acoustic response for the remaining frequency ranges (see fig. 2; abstract; column 5/lines 63-64; column 7/lines 6-11 & 14-23).

In regards to claim 19, Don disclose(s) an apparatus in which the processor is further programmed to predict the existence of a tumor from the result of step D (see figs. 1 & 15; abstract).

Although Don discloses an analysis method, Don does not disclose analysis steps comprising the steps of taking a transform. However, Devito discloses an EEG analysis method (see Abstract) comprising:

B) combining transforms of each of plural subsets of the complete set of frequencies; and

C) comparing the combined transforms found in step B with a transform of the complete set of frequencies in an EEG signal (see fig. 9; column 6/lines 62-67; column 7/lines 3-4, 11-13; column 7/line 65 to column 8/line 3; column 9/lines 4-10, 15-20 & 25-29).

In regards to claim 2, Devito disclose(s) a method in which the transform is a transform that results in a power spectrum of the frequencies contained in the response (see column 9/lines 4-10).

In regards to claim 4, Devito disclose(s) a method in which combining transforms comprises the steps of:

B1) finding a transform of each of plural subsets of the set of frequencies; and

B2) summing the transforms found in step B1 (see column 9/lines 15-20).

In regards to claim 5, Devito disclose(s) a method in which the transform is a transform that results in a power spectrum of the frequencies contained in the response (column 9/lines 4-10, 15-20 & 25-29).

In regards to claim 9, Devito disclose(s) a method in which comparing the sum of power spectra with the power spectrum of the set of frequencies in the acoustic response comprises normalizing the sum of power spectra to obtain a normalized sum and normalizing the power spectrum of the set of frequencies in the acoustic response to obtain a normalized reference and taking the ratio of the normalized sum and the normalized reference (see fig. 9; column 9/lines 4-10, 15-20 & 25-29).

In regards to claim 10, Devito disclose(s) a method in which a higher ratio of the normalized sum and the normalized reference corresponds to a higher probability of the existence of a tumor (column 9/lines 4-10, 15-20 & 25-29).

In regards to claim 11, Devito disclose(s) a method further comprising the step of comparing the ratio of the normalized sum and the normalized reference (see fig. 9).

In regards to claim 12, Devito disclose(s) a method further comprising the step of comparing the ratio of the normalized sum and the normalized reference to a ratio obtained from the opposite ear of an individual (see fig. 9).

In regards to claim 15, Devito disclose(s) a method in which a combination of the plural subsets of the complete set of frequencies comprises a wide band response (column 9/lines 4-10, 15-20 & 25-29).

In regards to claims 16 & 20, Devito disclose(s) a processor 50 connected to receive an EEG signal, the processor 50 being programmed to:

A) receive an EEG signal, the signal comprising a set of frequencies;

B) find a power spectrum for each of plural subsets of the set of frequencies;

C) sum the power spectra found in step B; and

D) compare the sum of the power spectra found in step C with the power spectrum of the set of frequencies in an EEG signal (see fig. 9; column 6/lines 62-67; column 7/lines 3-4, 11-13; column 7/line 65 to column 8/line 3; column 9/lines 4-10, 15-20 & 25-29).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Don with method steps similar to those of Devito in order to track changes in a subject's condition since an EEG power spectrum or ratios of EEG spectra are stable (i.e. control) parameters that can be used to accurately measure the physiological activity of a subject (see Devito, column 8/lines 25-36).

7. Claims 6-8, 10, 13-14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al. ('486) in view of Don ('616).

In regards to claims 6-7, 17 & 18, John et al. discloses a method, as described above, that teaches all the limitations of the claim except John et al. does not disclose masking a signal. However, Don discloses a method wherein:

In regards to claim 6 & 17, the subset of frequencies of the acoustic response comprises the auditory brainstem response in a set of limited frequency ranges found

by masking the acoustic response with white noise (see fig. 2; abstract; column 5/lines 63-64; column 7/lines 6-11 & 14-23).

In regards to claim 7 & 18, the subsets of the complete set of frequencies are found by the steps of:

obtaining an unmasked acoustic response;

obtaining masked acoustic responses by masking the stimulus with white noise in a frequency range;

subtracting the masked acoustic response of the highest frequency range from the unmasked frequency response to obtain a subset of the set of frequencies; and

subtracting the masked acoustic response from the next highest masked acoustic response for the remaining frequency ranges (see fig. 2; abstract; column 5/lines 63-64; column 7/lines 6-11 & 14-23).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of John et al. with method steps similar to those of Don in order to estimate the derived band auditory brainstem responses (see Don, column 7/lines 14-23).

In regards to claims 8, 10, 13-14 and 19, John et al. discloses a method, as described above, that teaches all the limitations of the claim except John et al. does not disclose the anomaly as being a tumor.

Moreover in regard to claim 14, John et al. disclose(s) a method in which the acoustic response is received differentially between a first electrode on the mastoid

corresponding to the stimulated ear and a second electrode (see column 8/lines 33-36; column 14/lines 41-47).

However, Don discloses a method Don disclose(s) a method in which the method is used to predict the existence of a tumor anomaly (see figs. 1 & 15; abstract).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of John et al. with method steps similar to those of Don in order to track changes in a subject's condition since an EEG power spectrum or ratios of EEG spectra are stable (i.e. control) parameters that can be used to accurately measure the physiological activity of a subject.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,003,986 to Finitzo et al. discloses a hierarchial analysis for processing brainstem signals to define a prominent wave.

US Patent No. 6,968,228 to Thornton discloses a measurement of electrophysiologic response.

US Patent No. 6,687,525 to Llinas et al. discloses a method and system for diagnosing and treating thalamocortical dysrhythmia.

US Patent No. 6,024,700 to Nemirovski et al. discloses a system and method for detecting a thought and generating a control instruction in response thereto.

US Patent No. 5,392,788 to Hudspeth discloses a method and device for interpreting concepts and conceptual thought from brainwave data and for assisting for diagnosis of brainwave dysfunction.

US Patent No. 5,230,344 to Ozdamar et al. discloses evoked potential processing system with spectral averaging, adaptive averaging, two dimensional filters, electrode configuration and method thereof.

US Patent Application Publication No. 2003/0144603 to Zoth et al. discloses a method and apparatus for automatic non-cooperative frequency specific assessment of hearing impairment and fitting.

US Patent Application Publication No. 2002/0091335 to John et al. discloses a brain function scan system.

US Patent No. 4,493,327 to Bergelson et al. discloses an automatic evoked potential detection.

US Patent No. 6,475,163 to Smits et al. discloses a hearing evaluation device with patient connection evaluation capabilities.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

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